DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-2, 40, 42, 43, 45-49, 52 and 81-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US 2003/0120257, hereinafter “Houston”) in view of Houston et al. (US 2004/0037986) and in further view of Popadiuk et al. (US 5,556,426, hereinafter "Popadiuk").

In regards to claim 1, Houston discloses introducing a helical formation into a flexible tubular material [abstract]. A side of the wall tube being deformed to form a helical formation in the internal surface of the side wall of the tube [0006]. The internal helical formations impart a helical flow to fluid passing through the tubular portion [0002-0003].

Houston discloses that after forming the helical formation, a polyurethane dispersion is applied to the corresponding indentation on the external side wall of the tubing [0034]. A former is then used to press the polyurethane into the material [0034]. The polyurethane is used to fill the external indentation of the internal helical formation [0034]. Thus, the internal helical protrusion comprises a section of the tubular portion deformed by an axially extending deformation helix.

Houston discloses that the correct helix angle of indentation is based on trial and error or whatever other appropriate grounds the best result in terms of elimination of turbulent flow and dead flow areas in and downstream of the implant [0039].

Houston is silent with the helix angle on the internal helical protrusion.

Houston et al. disclose a graft that has an internal helical protrusion with a helix angle between 5 degrees and 50 degrees [0013].

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the internal helix angle of Houston et al. in the internal helical protrusion of Houston, because the helix angle of Houston et al. provides the tubing with the best angle for liquid flowing through the tubing [0050].

The combination of Houston and Houston et al. is silent with regards to the external helical formation located around the outside of the tubular portion for supporting the tubular portion.

Popadiuk discloses a fluoropolymer filament wrapped helically around the external surface of a flexible implantable luminal device (abstract). The filaments may be wrapped around the central tube at angle of winding, relative to the axis, of from about 30 degrees to about less than 90 degrees (col. 9 lines 61-64). Thus, the filaments are wound around the tube at a different helix angle than the helix angle of the internal protrusions.

It would have been obvious to one of ordinary skill in the art to utilize helically wrapping a fluoropolymer filament as disclosed by Popadiuk around the external surface of a flexible tubular material of Houston, because the helically wrapped

fluoropolymer filament of Popadiuk provides reinforcement such that the tubes have superior physical characteristics, such as resistance to suture-induced tears and various types of deformation induced by extraneous stresses generated during implantation as well in situ (Popadiuk col. 3 lines 42-53).

In regards to claims 2 and 40, Houston discloses that the blood flow tubing may be a vascular graft [0003].

In regards to claim 45, Popadiuk discloses that the filaments may be wrapped around the central tube at angle of winding, relative to the axis, of from about 30 degrees to about less than 90 degrees (col. 9 lines 61-64), which is greater than the 16 degree angle of the internal helical formation disclosed by the combination of Houston and Houston et al.

In regards to claim 46, Houston et al. disclose a graft that has an internal helical protrusion with a helix angle between 5 degrees and 50 degrees [0013].

In regards to claim 47-48, Popadiuk discloses that the filaments may be wrapped around the central tube at angle of winding, relative to the axis, of from about 30 degrees to about less than 90 degrees (col. 9 lines 61-64).

In regards to claims 49, 83, 85 and 88, the combination of Houston and Houston et al. is silent with regards to the material used for the tubular portion.

Popadiux discloses that vascular grafts are generally made from fluoropolymers (col. 5 lines 54-67). The preferred fluoropolymer is PTFE (col. 6 line 8).

It would have been obvious to one of ordinary skill in the art to utilize PTFE in the tubular conduit as disclosed by Popadiux for the flexible material disclosed by the combination of Houston and Houston et al, because utilizing PTFE in the tubular conduit as disclosed by Popadiux produces a graft that is flexible, porous and capable of being extruded, stretched and sintered (col. 6 lines 1-5).

In regards to claims 81-82, 84 and 87, the combination of Houston, Houston et al. and Popadiux are silent with regards to the tubular portion made from specific materials.

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize any type of material that is known in the art, such as though disclosed in the claims to form the grafts of the combination of Houston, Houston et al., and Popadiux based on the intended purpose of the grafts and the aesthetic appeal to the consumer.

In regards to 86, Houston discloses that the external formation and the axially extending deformation helix are formed by deforming the material of the flexible tubular material. Thus, the external formation and the axially extending deformation would be comprised of the same material.

3. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US 2003/0120257, hereinafter “Houston”) in view of Houston et al. (US 2004/0037986) in further view of Popadiuk et al. (US 5,556,426, hereinafter "Popadiuk") and in further view of McHaney et al. (US 5,827,327, hereinafter “McHaney”).

The combination of Houston, Houston et al. and Popadiuk disclose the tubular conduit as previously discussed.

The combination of Houston, Houston et al. and Popadiuk is silent with regards to the inside having a carbon coating.

McHaney discloses a vascular graft which comprises carbon as an integral part of the wall of the tubular graft (col. 1 lines 8-14).

It would be obvious to one of ordinary skill in the art to combine the carbon coating of McHaney with the internal wall of the vascular graft of Caro, because the carbon coating of McHaney provides a vascular graft that exhibits a less thrombogenic blood contact surface with a minimal amount of carbon leaching and the carbon containing graft facilitates the binding of a time releasable bioactive substances, such as an anticoagulant or antimicrobial agent, to the graft (col. 2 lines 29-40).

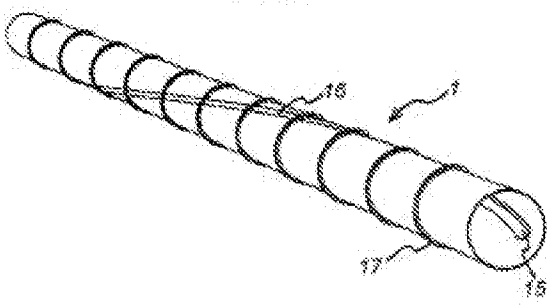
Response to Arguments

4. Applicant's arguments filed 06/17/2011 have been fully considered but they are not persuasive.

5. The applicant argues that the references do not teach, suggest, or motivated what amended claim 1 recites - namely, a tubular conduit: wherein the axially extending internal helical protrusion comprises a section of the tubular portion deformed by an axially extending deformation helix, and wherein the external helical formation the axially extending deformation helix are made from the same material.

In response, the applicant's fig. 2 describes an polyurethane deformation helix **16** whose outer surface lies substantially flush with the outer surface of the vascular graft **1** and which deforms the vascular graft **1** so as to provide the internal helical protrusion **15** (pg. 10 lines 12-15).

FIG. 2



Houston discloses an internal helical formation **11** [0030] which corresponds to the indentation on the external side of the wall of the material **12** [0034]. Thus, it can be seen through the figures that Houston discloses that the axially extending internal helical protrusion is deformed by an axially extending deformation helix and that the external helical formation and the axially extending deformation helix are made from the same material.

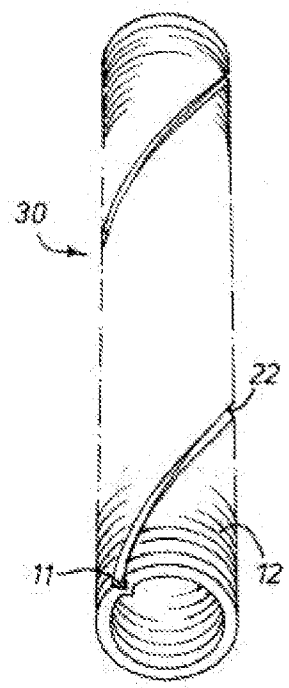


FIG 9

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLEN S. WOOD whose telephone number is (571)270-3450. The examiner can normally be reached on M-F 730-5 with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELLEN S WOOD/
Examiner, Art Unit 1782

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1782